



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,199	09/24/2001	Mitsuaki Yamamoto	213966US0PCT	6427
22850 7590 12/31/2007 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER FOSTER, CHRISTINE E	
			ART UNIT	PAPER NUMBER
			1641	
			NOTIFICATION DATE	DELIVERY MODE
			12/31/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 09/926,199	Applicant(s) YAMAMOTO ET AL.	
	Examiner Christine Foster	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 62-71, 73-84, 86-88 is/are pending in the application.
- 4a) Of the above claim(s) 63-70, 73-84 and 86-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 62 and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. In the interest of expediting prosecution, Applicant's submission of 12/13/07 is acknowledged and has been entered. However, Applicant is reminded of the manner of making amendments to the application. Specifically, it is noted that Applicant's amendment directs replacement of the abstract as well as two paragraphs of the specification; however, no markings are provided to indicate what changes are currently being made. Amendments to replace paragraphs of the specification must be accompanied by the full text of any replacement paragraph with markings to show all the changes relative to the previous version of the paragraph. In addition, it is noted that claim 74 has apparently been amended to recite "L- α -phosphatidyl" in line 2; however, no markings to indicate this change appear in the claim, which is presented with the status identifier "Previously Presented". All claims being currently amended must be presented with markings to indicate the changes that have been made relative to the immediate prior version. See MPEP 714.

2. Claim 62 was amended. Claims 72 and 85 were canceled. Accordingly, claims 62-71, 73-84, and 86-88 are pending in the application, with claims 63-70, 73-84 and 86-88 currently withdrawn. Claims 62 and 71 are subject to examination below.

Objections/Rejections Withdrawn

3. The objections to the specification not reiterated below have been withdrawn.
4. The objection to claim 62 has been obviated by the amendments thereto.

5. The rejection of claim 62 under § 112, 2nd paragraph has been withdrawn in response to Applicant's amendments to remove the term "polyoxyethylene higher alcohol ether".
6. The rejection of claim 62 under § 102(b) as being anticipated by Hino et al. in light of Hirai et al. has been withdrawn in response to Applicant's amendments to claim 62 to specify that the polyenes are selected from the recited Markush group.
7. The rejections of claims 62 and 71 on the grounds of nonstatutory obviousness-type double patenting over U.S. Patent No. 6,939,682 B2, and the provisional rejections over copending Application No. 11/184,117 have been withdrawn in response to Applicant's amendments.
8. The provisional rejections of claims 62 and 71 on the grounds of nonstatutory obviousness-type double patenting over copending Application No. 11/184,118 were in error as pointed out by Applicant (Reply, page 12) and accordingly, have been withdrawn.

Specification

9. The disclosure is objected to because of the following informalities:
10. Applicant's clarification is again requested regarding Applicant's desired amendments to the specification as presented in the amendment of 12/18/06. Specifically, the amendment includes the following instruction on page 2:

Page 4, line 25, replace "" [sic] with --SUMMARY OF THE INVENTION--.

Applicant's instructions are unclear. Specifically, is not clear what text should be replaced with the indicated header, since no text appears between the quotation marks indicated.

Clarification and/or correction are requested.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 62 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al. (“Ultrastructural localization of cholesterol by enzyme histochemistry” Histochem J. 1981 Nov;13(6):1017-28) in light of the evidence of Hirai et al. (US 4,940,660).

Jones et al. teach the following ingredients, which are used together in a method for localizing cholesterol: (1) digitonin (see in particular the abstract; page 1019, Table 1 and “Additional histochemical procedures”, page 1024, the first full paragraph of text; Figure 14; and pages 1026-1028, “Discussion”); (2) the surfactant Triton X-100, which is polyoxyethylene (10) octylphenyl ether in light of the evidence of Hirai et al. (see Hirai et al. at column 6, lines 55-57); see the abstract of Jones et al. and page 1018, “Incubation”); and (3) the enzymatic reagent that is cholesterol oxidase and cholesterol esterase (page 1018, “Incubation”). Jones et al. teach that the above ingredients are provided separately, where the sample is first incubated with cholesterol esterase and cholesterol oxidase (see page 1018, the first full paragraph and the section “Incubation”) followed by immersion in digitonin (page 1019); therefore, the reference anticipates the claimed invention.

Response to Arguments

13. With respect to the rejections of claims 62 and 71 under § 102(b) as being anticipated by Jones et al., Applicant's Arguments have been fully considered but are not persuasive of error. Applicant argues that Jones et al. fails to disclose or suggest the claimed reagent because there is no motivation to combine cholesterol oxidase and Triton X-100. As best understood, Applicant is arguing that the claimed reagent involves a physical combination or mixture of cholesterol oxidase and Triton X-100 (as opposed to a conceptual "motivation to combine" which would not be meaningful to the instant rejections under § 102). Applicant argues that Jones et al. teach two methods, the first relying on the enzymatic reagents cholesterol oxidase and cholesterol esterase and involving Triton X-100 and the second relying on digitonin and cholesterol esterase (see Reply, page 12).

This is not found persuasive because Applicant has not pointed to any language in the claims that would distinguish the claimed invention on this basis. The instant claims do not require cholesterol oxidase and Triton X-100 to be physically combined, e.g. as a mixture. Rather, the preamble of claim 62 indicates that the claimed reagent comprises the three ingredients "separately or as a mixture". Therefore, since Jones et al. teaches all elements of the claimed reagents, the reference is anticipatory.


Conclusion


14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Christine Foster
Patent Examiner
Art Unit 1641


LONG V. LE 12/17/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600